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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,398	01/23/2004	Christen M. Anderson	660088.443C1	4560

500 7590 04/26/2007
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
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EXAMINER

NIEBAUER, RONALD T

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,398	ANDERSON ET AL.	
	Examiner	Art Unit	
	Ronald T. Niebauer	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113-127 is/are pending in the application.
- 4a) Of the above claim(s) 113-115 and 117-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to the examiner's contact information listed at the end of this action.

Election/Restrictions

Applicant's election without traverse of Group I (claims 113-116) and species of SEQ ID NO:6 in the reply filed on 10/20/06, and clarification of the SEQ ID on 2/8/07 is acknowledged. Claim 116 reads on the elected species.

Claims 113-115, 117-127 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/20/06.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inventorship

In view of the papers filed 11/29/05, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Robert E. Davis as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 116 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 116 is drawn to an isoform-specific antibody that recognizes human ANT3. Page 67 of the specification provides direction and a working example for a method of

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making ANT3 antibodies using a small ANT3 peptide. A method of determining specificity is described on page 68-69. However, the specificity of the ANT3 antibody has not been shown so no support is provided that an isoform-specific antibody to ANT3 was possessed.

Section 2106 of the MPEP states:

For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention.

Further, section 2163 of the MPEP states:

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.

In the instant case, evidence is provided (Figure 3) that isoform specific antibodies were obtained for ANT1 and ANT2, but experimental evidence is not provided for ANT3. Further, the only identifying characteristic of the ANT3 isoform-specific antibody recited in the claim is a polypeptide sequence for the full-length ANT3 protein. The specification (page 67) provides the sequence of the peptide used for antibody generation but a mere sequence does not provide evidence of the functionality, which in this case is isoform-specificity. The peptide used has considerable similarity to human ANT2:

ANT3 peptide

Ser-Gly-Thr-Glu-Arg-Glu-Phe-Arg-Gly-Leu-Gly-Asp-Cys-Leu-Val-Lys-Ile-Thr

ANT2 sequence

Ala-Gly-Ala-Glu-Arg-Glu-Phe-Arg-Gly-Leu-Gly-Asp-Cys-Leu-Val-Lys-Ile-Tyr

One of skill in the art would not accept without question that the method described would give rise to ANT3 specific antibodies. Further, it has been shown even in the post

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filing date literature (Zamarin et al.) that there is a '...lack of availability of good antibodies specific for ANT3...' (page 0047, beginning of 3rd full paragraph). Taken together there is not sufficient written description to reasonably convey possession of an isoform-specific antibody for ANT3.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 116 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Zhang et al. (abstract) teach that autoantibodies to ANT are made in nature. The naturally occurring autoantibodies are polyclonal, and thus represent a collection of antibodies directed to many epitopes. It is reasonable to believe that there are some naturally-occurring epitopes which are specific to ANT3, and therefore reason to believe that the autoantibodies include some which are specific to ANT3. Therefore the claim, as written, appears to read upon a product of nature. It would be remedial to amend the claim to recite 'an isolated antibody'.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 116 is rejected under 35 U.S.C. 102(b) as being anticipated by Doerner et al. (Mol. Cell. Bio.) as evidenced by Doerner et al. (FEBS Letters).

Claim 116 recites an isoform-specific antibody that recognizes a human adenine nucleotide translocator 3 polypeptide of SEQ ID NO:6.

Doerner et al. (Mol. Cell. Bio.) teach antibodies made against total myocardial ANT protein (page 262 section Determination of ANT protein and figure 2). Doerner et al. (FEBS Letters, as cited in IDS) teach that ANT1, ANT2, and ANT3 mRNA is present in hearts (figure 3) so it would be inherent that ANT1, ANT2, and ANT3 protein are present in hearts. The antibodies described (Doerner et al. (Mol. Cell. Bio.)) appear to be polyclonal antibodies and thus represent a collection of antibodies directed to many epitopes. It is reasonable to believe that there are some naturally-occurring epitopes which are specific to myocardial ANT3 and therefore reason to believe that the reference antibodies include some which are specific to ANT3. Therefore, the claimed ANT3 specific antibodies are reasonably concluded to be anticipated by antibodies in the prior art polyclonal mixture.

Conclusion

No claims are allowed.

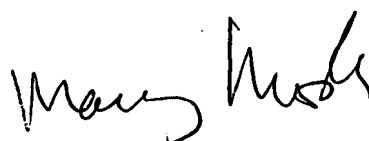
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-

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270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MARY MOSHER
SUPERVISORY PATENT EXAMINER

4-24-07